1997 UPDATE:

ELECTRICAL STIMULATION FOR THE TREATMENT OF CHRONIC WOUNDS

In preparing this update, ECRI searched the following databases: Current Contents, Federal Research in Progress, Medline, Healthcare Standards (ECRI), Health Device Alerts (ECRI), Health Devices Sourcebook (ECRI), and International Health Technology Assessment (ECRI). Our findings are current as of January 1997. All search strategies were previously described in the original technology assessment.

Search results identified two additional studies:

- Baker et al. 1996—a randomized controlled trial of alternating current electrical stimulation versus sham therapy for heterogeneous lesions (i.e., decubitus and surgical lesions) and
- Kenkre et al. 1996—a double-blind randomized trial of pulsed electromagnetic stimulation versus sham therapy for venous leg ulcers.

Examination of these studies did not lead us to change our previous conclusions. We could not calculate normalized healing rates for either study, and because of the studies' poor quality, there was insufficient reason to include them in the previously performed meta-analysis. Nonetheless, we have adjusted existing tables and text to include these studies.

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
1.0	Executive Summary	No changes
2.0	Healing Process and Ulceration	—
2.1	Phases of Wound Healing	No changes
2.2	Wounds and Ulcerations	No changes
2.3	Evaluation and Therapies for Wound Healing	—
2.3.1	Evaluation	No changes
2.3.2	General Therapies	No changes
2.4	Guidelines and Evidence of Present Practice Patterns	No changes
2.4.1	Consensus	No changes
2.4.2	Lack of Consensus	No changes
2.4.3	Practice Patterns	No changes
2.5	Tables 2.1 through 2.3	No changes
3.0	Electrical Stimulation for Wound Healing	—
3.1	Basic Description	No changes
3.2	Types of Electrical Stimulation and Treatment Protocols	No changes
3.2.1	Direct Current Applications	No changes
3.2.2	Pulsed Current Applications	No changes
3.2.3	Alternating Current Applications	Addition of 1996 study by Baker et al.[1] to 2nd paragraph of page 39
3.2.4	Pulsed Electromagnetic Applications	Alteration in 1st paragraph of page 41; addition of 1996 study by Kenkre et al.[2] to new 2nd paragraph of page 41
3.2.5	Spinal Cord Stimulation Applications	Changes in 1st paragraph of section on page 41
3.3	Safety	—
3.3.1	Reports from Published Studies	No changes
3.3.2	Contraindications and Warnings from Product Literature	No changes
3.3.3	ECRI Health Device Alerts Database	No changes

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
3.4	Manufacturers and Costs	No changes
3.5	Tables 3.1 through 3.3	No changes
	Table 3.4	Addition of 1996 study by Baker et al.[3] to table on page 54
	Table 3.5	Addition of 1996 study by Kenkre et al.[4] to table on page 56
	Table 3.6	No changes
4.0	Quality of Electrical Stimulation Studies for Chronic Wound Healing	No changes
4.1	Databases and Search Strategies for Electrical Stimulation Studies	Updating of database searches on page 74
4.2	Possible Confounding Factors in Wound Healing Studies	No changes
4.2.1	Study Types	No changes
4.2.2	Confounding Sources	No changes
4.2.3	Outcome Measures	No changes
4.2.3.1	Objective Outcomes: Percentage of Patients Completely Healed	No changes
4.2.3.2	Objective Outcomes: Healing Rates	No changes
4.2.3.3	Subjective Outcomes	No changes
4.3	Quality of Individual Electrical Stimulation Studies of Wound Healing	No changes
4.3.1	Direct Current Controlled Studies	No changes
4.3.2	Pulsed Current Controlled Studies	No changes
4.3.3	Alternating Current and TENS Controlled Studies	Addition of summary of quality for 1996 study by Baker et al.[5] on page 92
4.3.4	Pulsed Electromagnetic Induction Controlled Studies	Addition of summary of quality for 1996 study by Kenkre et al.[6] on page 94
4.3.5	ES Study Quality: General Findings	No changes
4.4	Tables 4.1 through 4.2	No changes
	Table 4.3	Addition of 1996 study by Baker et al.[7] to table on page 100
	Table 4.4	Addition of 1996 study by Kenkre et al.[8] to table on page 102

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
5.0	Electrical Stimulation Study Descriptions and Outcomes	No changes
5.1	Direct Current Studies	—
5.1.1	Uncontrolled Studies	No changes
5.1.2	Controlled Studies	No changes
5.2	Pulsed Current Studies	—
5.2.1	Uncontrolled Studies	No changes
5.2.2	Controlled Studies	No changes
5.3	Alternating Current (and TENS) Studies	—
5.3.1	Uncontrolled Studies	No changes
5.3.2	Controlled Studies	Addition of description for 1996 study by Baker et al.[9] on page 116
5.4	Pulsed Electromagnetic Induction Studies	—
5.4.1	Uncontrolled Studies	No changes
5.4.2	Controlled Studies	Addition of description for 1996 study by Kenkre et al.[10] on page 119
5.5	Spinal Cord Stimulation Studies	—
5.5.1	Uncontrolled Studies	No changes
5.5.2	Controlled Studies	No changes
5.6	Ongoing Studies	No changes
5.7	Tables 5.1 through 5.2	No changes
	Table 5.3	Addition of 1996 study by Baker et al.[11] to table on page 126
	Table 5.4	Addition of 1996 study by Kenkre et al.[12] to table on page 128
	Tables 5.5 through 5.6	No changes
6.0	Quantitative Analysis and Meta-Analyses of Outcomes of Electrical Stimulation Studies	No changes
6.1	Quantitative Analysis of Normalized Wound Healing Rates: Theta (?) Values	—
6.1.1	Definition and Description of Theta	No changes
6.1.2	Theta Outcomes for Individual Electrical Stimulation Studies	No changes to text (but see Tables 6.3 and 6.4 for changes)

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
6.1.3	Summary of Normalized Healing Rates for Electrical Stimulation Studies	No changes
6.2	Meta-Analyses of Outcomes of Electrical Stimulation for Wound Healing	—
6.2.1	Overview of Meta-Analytic Methods	No changes
6.2.2	Meta-Analysis of Normalized Wound Healing Rates	No changes
6.2.2.1	Overall Study Analysis	No changes
6.2.2.2	Analysis of Study Heterogeneity	No changes
6.2.2.2.1	Influence of Study Design	No changes
6.2.2.2.2	Influence of Patient Characteristics, Wound Characteristics, or Treatment	No changes
6.2.3	Meta-Analysis of Complete Wound Healing	Slight change to text
6.2.3.1	Overall Study Analysis	No changes
6.2.3.2	Analysis of Study Heterogeneity	No changes
6.2.3.2.1	Influence of Study Design	No changes
6.2.3.2.2	Influence of Patient Characteristics, Wound Characteristics, or Treatment	No changes
6.2.4	Publication Bias	No changes
6.2.5	Conclusions of Meta-Analyses of Electrical Stimulation for Wound Healing	No changes
6.3	Figures 6.1 through 6.2	No changes
	Tables 6.1 through 6.2	No changes
	Table 6.3	Addition of 1996 study by Baker et al.[13] to table on page 158
	Table 6.4	Addition of 1996 study by Kenkre et al.[14] to table on page 159
	Table 6.5	Addition of 1996 study by Baker et al.[15] and Kenkre et al.[16] to table on page 160
	Tables 6.6 through 6.7	No changes
	Figure 6.3	No changes
	Tables 6.8 through 6.9	No changes
	Figures 6.4 through 6.6	No changes

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
7.0	Quality of Study Comparison: Electrical Stimulation versus Conventional and Alternative Therapies for Wound Healing	No changes
7.1	Quality Comparison for Venous Ulcers	—
7.1.1	Comparison with Conventional Therapies	No changes
7.1.2	Comparison with Alternative Therapies	No changes
7.2	Quality Comparison for Decubitus Ulcers	—
7.2.1	Comparison with Conventional Therapies	No changes
7.2.2	Comparison with Alternative Therapies	No changes
7.3	Tables 7.1 through 7.8	No changes
8.0	Comparison of Normalized Healing Rates: Electrical Stimulation versus Conventional and Alternative Therapies for Wound Healing	No changes
8.1	Comparison of Normalized Healing Rates for Venous Ulcers	—
8.1.1	Comparison with Conventional Therapies	No changes
8.1.2	Comparison with Alternative Therapies	No changes
8.2	Comparison of Normalized Healing Rates for Decubitus Ulcers	—
8.2.1	Comparison with Conventional Therapies	No changes
8.2.2	Comparison with Alternative Therapies	No changes
8.3	Tables 8.1 through 8.8	No changes
9.0	General Summary	—
9.1	Basic Description of Electrical Stimulators	No changes
9.2	Analyses of Electrical Stimulation Studies	—
9.2.1	Quality of Electrical Stimulation Studies	Slight change to text in 1st paragraph on page 213
9.2.2	Quantitative Analysis of Electrical Stimulation: Normalized Healing Rates	No changes
9.2.3	Meta-Analyses of Electrical Stimulation Studies	No changes

SUMMARY OF CHANGES FOR EACH SECTION OF REPORT:

Section Number	Section Title	Changes to "Electrical Stimulation for the Treatment of Chronic Wounds" (April 1996; document #286196)
9.3	Comparison of Electrical Stimulation Studies with Other Therapies for Wound Healing	—
9.3.1	Comparison of Qualities of Studies	No changes
9.3.2	Comparison of Normalized Healing Rates	No changes
10.0	Appendix I: List of Abbreviations	No changes
11.0 (all subsections)	Appendix II: Formulae Used in Meta-Analyses	No changes
12.0	Appendix III: AHCPR Strength-of-Evidence Rating System	No changes
13.0	Appendix IV: External Reviewer Comments	No changes

3.2.3 Alternating Current Applications

[Page 39—beginning with second paragraph, "Biphasic AC studies . . . "]

Biphasic AC studies typically used 15 to 25 mA with 0.25 ms pulses at 40 Hz frequency. Biphasic AC studies include Stefanovska et al., Karba et al., and Baker et al.[17]

Representative Biphasic AC Regimen: Stefanovska et al. 1993

(1) A biphasic, charge-balanced AC stimulus was applied with a 0.25 ms pulse duration at 40 Hz. Four-second stimulation trains were rhythmically alternated with four-second pauses. The AC amplitude was kept between 15 and 25 mA to prevent damage to newly formed tissue and to minimize tetanic contraction of stimulated tissues.

(2) Daily sessions lasted two hours and were continued until lesions healed.

3.2.4 Pulsed Electromagnetic Applications

[Page 41—beginning with first paragraph, "PEE studies used . . . "]

PEE Regimen:*

PEE studies used primarily Diapulse® devices. These devices emit a nonthermal, pulsed, high-frequency, high peak power electromagnetic energy delivered at 27.12 MHz, with a pulse repetition rate of 80 to 600 pulses/second and a 65 μsec pulse width, and produce 273 to 975 W per pulse, with a 0.5% to 4.0% duty cycle. Energy is induced at the wound site by a 9″ drum-shaped treatment head placed in light contact with the dressing and tuned to resonance with the wound site. Recommended treatment consists of 30 minutes, twice daily, until the lesion is healed. As with PEMF devices, the device is applied externally over existing dressings. PEE studies include Salzberg et al., Tung et al., Itoh et al., and Goldin et al. Therapies generally consisted of 30-minute sessions twice daily for 8 to 12 weeks or until the lesion healed.

Another study by Kenkre et al.[18] used a device (Elmedistraal) that appears to be similar.

* Diapulse refers to their device as a nonthermal pulsed high-frequency high peak power electromagnetic energy device (NT/PHF). This acronym does not appear in the literature.

3.2.5 Spinal Cord Stimulation Applications

[Page 41—first paragraph of subsection beginning, “Spinal cord stimulators...”]

Spinal cord stimulators are primarily designed to reduce intractable pain in patients with failed back syndrome and other chronically painful disorders. (See ECRI Technology Assessment “Spinal Cord [Dorsal Column] Stimulation for Chronic Intractable Pain” and more recent updates on neurologic applications [“Spinal Cord Stimulation; I: Neurologic Applications”[19] and peripheral vascular and cardiovascular applications [“Spinal Cord Stimulation; II: Peripheral Vascular and Cardiology Application.”[20] These devices significantly differ from the types of electrical stimulators previously mentioned for wound healing because spinal cord stimulators are (a) invasive and (b) not primarily intended to increase the rate of wound healing.

Table 3.4. Synopses of Alternating Current (AC) Stimulation Therapies for Wound Healing

Study	Type of Alternating Current Stimulation	Therapy Synopsis
Baker et al.[21] (1996)	Biphasic AC	Biphasic AC current in randomized controlled study: group 1 (amplitude below muscle contraction level, 100 µs phase duration, 50 Hz), group 2 (amplitude below muscle contraction level, 300 µs, 50 Hz), group 3 (4 mA amplitude, 10 µs, 1 Hz), and a control group (placebo, no stimulation); 30-minute sessions TID up to 4 weeks or healing Device Manufacturer: UltraStim, Henley International, Houston, TX
Stefanovska et al. (1993)	Biphasic AC	Biphasic AC current of 15 to 25 mA with charge-balanced current stimuli with 0.25 ms pulse duration @ 40 Hz; 2 hr daily sessions [Device not specified]
Lundeberg et al. (1992)	Electrical nerve stimulation (ENS) unit	AC (alternating constant-current square-wave pulses) of 1 ms pulse width @ 80 Hz applied just outside ulcer surface area—at current sufficient to produce paresthesia—for 20-minute sessions BID; polarity changed after each session Device Manufacturer: Delft Instruments, The Netherlands and/or Henley International, Houston, TX
Karba et al. (1991)	Biphasic AC	Biphasic AC current of 15 to 25 mA with charge-balanced current stimuli with 0.25 ms pulse duration @ 40 Hz; amplitude adjusted for each individual patient; 60-minute daily sessions [Device not specified]
Frantz (1990)	TENS	Constant square-wave pulses of 30 mA @ 85 Hz (150 µs pulse width); 1 set of electrodes on hands, other set proximal (anode) or distal (cathode) to lesions; applied for 30-minute sessions TID Device Manufacturer: Medtronic Eclipse Plus Model 7723 TENS
Kjartansson and Lundeberg (1990)	Electrical nerve stimulation (ENS) unit	Monopolar square wave pulses with duration of 0.2 ms @ 90 Hz Device Manufacturer: TENS unit (Delta, U.K.)
Kaada and Emru (1988)	TENS	Pocket stimulator delivering pulse trains (to electrodes in gauze around lesion) @ 2 Hz, 25 to 50 mA stimulation intensity, delivering constant square-wave pulses at 100 Hz internal frequency and 0.1 to 0.2 ms duration Device Manufacturer: Viking Single (Medi-Stim A/S, Oslo, Norway)
Lundeberg et al. (1988)	Electrical nerve stimulation (ENS) unit	Alternating square-wave pulses 0.4 ms duration @ 80 Hz; stimulus intensity set to 3 times threshold in which tingling sensation felt by patient; 2 hr sessions BID Device Manufacturer: ENS unit (Enraf-Nonius, Netherlands)
Alon et al. (1986) [Abstract]	TENS	Continuous mode @ 80 Hz; positive electrode (in sterile gauze) over ulcer site [Device not specified]

Table 3.4. Synopses of Alternating Current (AC) Stimulation Therapies for Wound Healing (continued)

Study	Type of Alternating Current Stimulation	Therapy Synopsis
Barron et al. (1985)	Percutaneous low-energy non-galvanic stimulator [TENS]	Modified biphasic square wave: 600 µA, 50 V @ 0.5 Hz administered percutaneously across ulcer surface; 3 sessions TID for 3 wks Device Manufacturer: Micro-Electro Medical Stimulation
Kaada (1983)	TENS	Constant square wave pulses of 15 to 30 mA (intensity increased until local contraction of adjacent muscles without producing pain), each stimulus consisting of bursts of 5 pulses with 100 Hz internal frequency; 30- to 45-minute sessions TID; 1 set of electrodes on hands, other set proximal (anode) or distal (cathode) to lesions; all applied from pocket stimulator [Device not specified]
Westerhof and Bos (1983)	TENS	120 Hz, 250 µs pulse width, 0.5 sec pulse train envelope, 0.5 pulse train interval; 30-minute sessions TID Device Manufacturer: Bio-Medical Research P_8 unit

BID = two times a day
TID = three times a day

Table 3.5. Synopses of Pulsed Electromagnetic Induction (PEMI) Stimulation Therapies for Wound Healing

[Page 56—addition of Kenkre et al. 1996 to table]

Study	Type of Electromagnetic Stimulation	Therapy Synopsis
Kenkre et al.[22] (1996)	PEE	Electromagnetic device generating perpendicular electric and magnetic fields, delivered through a pulse generator at 100, 600, or 800 Hz; pulsed current supplied to pair of electromagnetic electrodes generating magnetic field of 25 µT; 30-minute sessions daily for 5 days/week Device: Elmedistraal
Salzberg et al. (1995)	PEE	Pulsed, nonthermal, high-frequency, high peak power electromagnetic energy delivered at 27.12 MHz, pulse repetition rates of 80 to 600 pulses/sec, 65 µs pulse width, 293 to 975 W per pulse peak, 0.5 to 3.9% duty cycle; treatment head placed in contact with wound site and tuned to resonance in area of wound; 30-minute sessions BID Device Manufacturer: Diapulse® (Diapulse Corp. of America, Great Neck, NY)
Tung et al. (1995)	PEE	Same device parameters as Salzberg et al.; applied in case reports Device Manufacturer: Diapulse® (Diapulse Corp. of America, Great Neck, NY)
Stiller et al. (1992)	PEMF	Electromagnetic transducer (attached to signal generator 9 V battery) containing coils for magnetic focusing strapped over wound dressing with elasticized Velcro strap; induces low level, nonthermal electrical field of approx. 0.06 mV/cm; has 3-part pulse of 3.5 ms total width, 25% duty cycle, 22 Gauss; applied (at home) 3 hrs/day on top of dressing for 8 to 12 wks (or healing) Device Manufacturer: PELUT* System (Geomed, Inc.)
Todd et al. (1991)	PEMF	Active coils in Helmholtz arrangement; ulcer placed between coils connected to magnetic field generator; field strength = 60, intensity = 5 Hz; 15-minute sessions performed twice/week for 5 wks after initial 2 wks on standard ulcer therapy [Device not specified]
Itoh et al. (1991)	PEMF	Same device parameters as Salzberg et al.; applied directly through dressings at 600 pulses/sec and 6 peak power; 30-minute sessions BID (8-hour separation between sessions) until healed Device Manufacturer: Diapulse® (Diapulse Corp. of America, Great Neck, NY)

Table 3.5. Synopses of Pulsed Electromagnetic Induction (PEMI) Stimulation Therapies for Wound Healing (continued)

Study	Type of Electromagnetic Stimulation	Therapy Synopsis
Ieran et al. (1990)	PEMF	Stimulators supplied electromagnetic coils with a single pulse of electrical current generating magnetic field of 2.8 mT @ 75 Hz and 1.3 ms pulse width; patients instructed to use stimulators at home 3-4 hrs/day for 90 days or until healed Device Manufacturer: Dermagen, Igea (Carpi, Italy)
Jeran et al. (1987)	PEMF	Stimulation parameters in electromagnetic coils: maximum magnetic field = 2.7 mT, 75 Hz, 1.3 ms pulse width; patients instructed to use stimulators at home 4 hrs/day for 90 days or until healed Device Manufacturer: Dermagen, Igea (Carpi, Italy)
Goldin et al. (1981)	Pulsed “radio energy”	Peak output of 975 W @ 400 pulses/sec, 65 μs average pulse duration, mean energy output with 3 cm depth penetration; 30-minute application to graft donor site at time of premedication and 6 hours postoperatively Device Manufacturer: Diapulse® (Diapulse Corp. of America, Great Neck, NY)

* PELUT = pulsed electromagnetic limb ulcer therapy
BID = 2 times a day

4.1 Databases and Search Strategies for Electrical Stimulation Studies

[Page 74—updating of searches]

External databases searched by ECRI are:

- Ageline (1966 through December 1995)
- Biosis Previews (1969 through December 1995)
- Catline (1985 through December 28, 1995)
- Ei Compendex Plus (1970 through December 1995)
- Current Contents (January 1994 through January 1997)
- Diogenes (1976 through January 4, 1996)
- Dirline (1985 through December 1995)
- Embase (1974 through November 11, 1995)
- Federal Research in Progress (January 1996; updated monthly)
- Health Planning and Administration (1975 through December 19, 1995)
- Health Services/Technology Assessment Research (1985 through December 19, 1995)
- INSPEC (1969 through December 1995)
- International Health Technology Assessment (1990 through January 4, 1996)
- MEDLINE (1966 through January 10, 1997)
- Nursing and Allied Health (1984 through December 19, 1995)

ECRI proprietary databases searched are:

- Health Care Standards (1990 through January 1997)
- Health Device Alerts (1977 through January 1997)

- Health Devices Sourcebook (January 1997)
- International Health Technology Assessment (1990 through January 1997)

4.3.3 Alternating Current and TENS Controlled Studies

[Page 92—addition of Baker et al. 1996 study]

(1) Baker et al. (1996)[23]—Single-blinded RCT of asymmetrical biphasic AC versus symmetrical biphasic AC versus minimal stimulation control group versus sham group for spinal cord injury patients with decubitus ulcers or surgical ulcers

- Used patients with different types of lesions (i.e., decubitus and surgical ulcers)
- Possibly confounded by infected lesions
- Possibly confounded by topical/cleansing agents or dressings
- Stage of lesions not specified
- Randomization method not specified
- Lesions expressed in surface area alone (although investigators attempted to determine volume of lesions)
- No vascular perfusion testing before therapy
- Did not specify whether patients with diabetes or rheumatoid arthritis were included or excluded from study
- Did not specify steroid use or nutritional status of patients

(2) Stefanovska et al. (1993)—RCT of biphasic AC versus LIDC versus conventional therapy for decubitus lesions

- Randomization method not specified
- Stage of lesions not specified
- Lesions expressed in surface area alone
- No vascular perfusion testing before therapy
- Did not specify whether patients with infected lesions, with diabetes, or with rheumatoid arthritis were included or excluded from study
- Did not specify steroid use or nutritional status of patients

- Did not specify any concomitant therapy (e.g., debridement, use of topical or cleansing agents, dressings, antibiotics)

(3) Lundeberg et al. (1992)—Double-blind RCT of TENS versus sham (placebo) unit for diabetic ulcerations

- Did not specify patient age or duration of lesions
- Lesions expressed in surface area alone
- Did not specify whether patients with infected lesions were included or excluded from study
- Did not specify steroid use or nutritional status of patients

4.3.4 Pulsed Electromagnetic Induction Controlled Studies

[Page 93—addition of Kenkre et al. 1996 study]

(1) Kenkre et al. (1996)[24]—Double-blinded RCT of PEE device (at 600 Hz and 800 Hz) versus sham (placebo) unit for venous ulcers

- Possibly confounded by statistically significant age differences between one treatment group and placebo group
- Did not specify gender of groups
- Lesions expressed in surface area alone
- Did not specify whether patients with diabetes or rheumatoid arthritis were included or excluded from study
- Did not specify steroid use or nutritional status of patients

(2) Salzberg et al. (1995)—Double-blind RCT of PEE device versus sham (placebo) unit for decubitus ulcers

- Randomization method not specified
- Did not specify patient age, anatomical location of lesions, or duration of lesions
- Lesions expressed in surface area alone
- No vascular perfusion testing before therapy
- Did not specify whether patients with peripheral arterial or venous disease, with diabetes, or with rheumatoid arthritis were included or excluded from study
- Did not specify steroid use of patients

(3) Stiller et al. (1992)—Double-blind RCT of PEMF device versus sham (placebo) unit for venous ulcers

- Lesions expressed in surface area alone
- Did not specify whether patients with infected lesions or with rheumatoid arthritis were included or excluded from study

- Did not specify steroid use of patients
- Possibly confounded by debridement therapy, use of dressings, and antibiotic therapy

(4) Todd et al. (1991)—Double-blind RCT of PEMF versus sham (placebo) unit for venous ulcers

- Small study (≤10 patients per treatment group)
- Randomization method not specified
- Lesions expressed in surface area alone
- Did not specify whether patients with diabetes or with rheumatoid arthritis were included or excluded from study
- Did not specify steroid use or nutritional status of patients

(5) Ieran et al. (1990)—Double-blind RCT of PEMF versus sham (placebo) unit for venous ulcers

- Lesions expressed in surface area alone
- Did not specify whether patients with infected lesions or with rheumatoid arthritis were included or excluded from study
- Did not specify nutritional status of patients
- Possibly confounded by inclusion of patients with diabetes in study
- Possibly confounded by antibiotic therapy used in study

(6) Jeran et al. (1987)—Double-blind RCT of PEMF versus sham (placebo) unit for venous ulcers

- Randomization method not specified
- Did not specify patient age or gender
- Lesions expressed in surface area alone
- No vascular perfusion testing before therapy

- Did not specify whether patients with peripheral arterial disease, with diabetes, or with rheumatoid arthritis were included or excluded from study
- Did not specify steroid use or nutritional status of patients
- Possibly confounded by inclusion of infected lesions in study
- Possibly confounded by antibiotic therapy used in study

Table 4.3. Assessment of Quality of Alternating Current Stimulation Studies of Wound Healing
[Page 100—addition of Baker et al. 1996 study]

Study Specified...	Baker[25]	Stefanovska	Lundeberg	Karba	Frantz	Kaada	Alon [Abstract]	Barron
Stimulation Type	Biphasic AC[a]	Biphasic AC	(T)ENS	Biphasic AC	TENS	TENS	TENS	TENS
Wound	Decubitus + Surgical	Decubitus	Diabetic	Decubitus + Vascular + Surgical	Decubitus	Leper (tuberculoid + lepromatous)	Diabetic	Decubitus
Homogeneous	No	Yes	Yes	No	Yes	Yes	Yes	Yes
N (Patients or Lesions)	80 patients[b] (192 lesions)	150	64	63	4	32	15	6
Study Type	RCT	RCT	Double-blind RCT	Case series	Case series (Pilot study)	Case series	Case series	Case series
Randomization	No	No	Yes	—	—	—	—	—
Patients Blinded	Yes	?	Yes	—	—	—	—	—
Clinicians Blinded	No	No	Yes	—	—	—	—	—
Patient Age	By group	By group + variance	No	No	By group	By subject	By group	By subject
Gender	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Location of Lesions	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes
Duration of Lesions	By group	By group + variance	No	By group + variance	By group	By subject	By group	By subject
Stage of Lesions	No	No	No	No	No	No	No	No
Specified Previous Therapy	No	No	No	Yes	No	Yes	No	Yes
Size of Lesions	Surface area[c]	Surface area	Surface area	Surface area	Surface area + circumference	Surface area + volume	Surface area	Surface area
Initial Size of Lesions	By group + variance	By group + variance	By group + variance	By group + variance	By subject	By subject	No	By subject
Pre-tx Vascular Perfusion Performed	No	No	Yes	No	No	No	No	No
Inclusion criteria considered:								
Infection	Yes	No	No	No	Yes	No	No	Yes
PAD/PVD	Yes	Yes	Yes	Yes	No	Yes	No	No
Diabetes	No	No	Yes	Yes	No	Yes	Yes	No
Rheumatoid Arthritis	No	No	Yes	No	No	No	No	No
Steroids	No	No	No	No	No	No	No	No
Nutrition	No	No	No	No	Yes	No	No	No

Table 4.3. Assessment of Quality of Alternating Current Stimulation Studies of Wound Healing (continued)

Study Specified...	Baker[25]	Stefanovska	Lundeberg	Karba	Frantz	Kaada	Alon [Abstract]	Barron
Possible confounding by:								
Infection	Yes	No	No	No	No	No	No	No
PAD/PVD	No	No	No	No	No	No	No	No
Diabetes	No	No	No	No	No	No	No	No
Rheumatoid Arthritis	No	No	No	No	No	No	No	No
Steroids	No	No	No	No	No	No	No	No
Nutrition	No	No	No	No	No	No	No	No
Specified use of:								
Debridement	No	No	No	No	No	No	No	No
Topical/Cleansing Agents	Yes	No	Yes	No	No	Yes	No	No
Dressings	Yes	No	Yes	No	Yes	Yes	Yes	No
Pressure Devices	No	No	NA	No	No	NA	No	No
Antibiotics	No	No	No	No	No	No	No	No
Possible confounding by:								
Debridement	No	No	No	No	No	No	No	No
Topical/Cleansing Agents	Yes	No	No	No	No	No	No	No
Dressings	Yes	No	No	No	Yes	No	No	No
Pressure Devices	No	No	No	No	No	No	No	No
Antibiotics	No	No	No	No	No	No	No	No

[a] Asymmetric and symmetric types
[b] Patients primarily with spinal cord injuries (partial or complete)
[c] Attempted to measure volume of lesions, but found it infeasible
Group + variance = study specified some measure of variance
Excluded: Finsen et al. (background study)
Lundeberg et al. (background study)
Kjartansson et al. (background study)
Kaada (case report)
Westerhof and Bos (case report)

Table 4.4. Assessment of Quality of Pulsed Electromagnetic Induction Studies of Wound Healing
[Page 102—addition of Kenkre et al. 1996 study]

Study Specified...	Kenkre[26]	Salzberg	Stiller	Todd	Itoh	Ieran	Jeran
Stimulation Type	PEE	PEE	PEMF	PEMF	PEE	PEMF	PEMF
Wound	Venous	Decubitus	Venous	Venous	Decubitus	Venous	Venous
Homogeneous	Yes	Yes	Yes	Yes	Yes	No	Yes
N (Patients or Lesions)	19	20	31	19	22	37	21
Study Type	Double-blind RCT	Double-blind RCT	Double-blind RCT	Double-blind RCT	Case series	Double-blind RCT	Double-blind RCT
Randomization	No	No	Yes	No	—	Yes	No
Patients Blinded	Yes	Yes	Yes	Yes	—	Yes	Yes
Clinicians Blinded	Yes	Yes	Yes	Yes	—	Yes	Yes
Patient Age	By group[a]	By group	By group	By group	By subject	By group	No
Gender	No	No	Yes	Yes	Yes	Yes	No
Location of Lesions	Yes	No	Yes	Yes	Yes	Yes	Yes
Duration of Lesions	By group	No	By group + variance	By group	By group	By group	Yes
Stage of Lesions	No	Yes	No	No	Yes	No	No
Specified Previous Therapy	Yes	No	Yes	No	Yes	No	No
Size of Lesions	Surface area	Surface area	Surface area	Surface area	Surface area	Surface area	Surface area
Initial Size of Lesions	By group	By subject	By group + variance	By group	By subject	By group	By group

Table 4.4. Assessment of Quality of Pulsed Electromagnetic Induction Studies of Wound Healing (continued)

Study Specified...	Kenkre[26]	Salzberg	Stiller	Todd	Itoh	Ieran	Jeran
Pre-tx Vascular Perfusion Performed	Yes	No	Yes	Yes	No	Yes	No
Inclusion criteria considered:							
Infection	Yes	Yes	No	Yes	No	No	Yes
PAD/PVD	Yes	No	Yes	No	No	Yes	No
Diabetes	No	No	Yes	No	No	Yes	No
Rheumatoid Arthritis	No	No	No	No	No	No	No
Steroids	No	No	No	No	No	Yes	No
Nutrition	No	Yes	Yes	No	Yes	No	No
Possible confounding by:							
Infection	No	No	No	No	No	No	Yes
PAD/PVD	No	No	No	No	No	No	No
Diabetes	No	No	No	No	No	Yes	No
Rheumatoid Arthritis	No	No	No	No	No	No	No
Steroids	No	No	No	No	No	No	No
Nutrition	No	No	No	No	No	No	No
Specified use of:							
Debridement	No	No	Yes	No	No	No	No
Topical/Cleansing Agents	No	No	Yes	Yes	Yes	No	No
Dressings	No	Yes	Yes	Yes	Yes	No	No
Pressure Devices	No	No	NA	NA	Yes	NA	NA
Antibiotics	No	No	Yes	Yes	Yes	Yes	Yes
Possible confounding by:							
Debridement	No	No	Yes	No	No	No	No
Topical/Cleansing Agents	No	No	No	No	Yes	No	No
Dressings	No	No	Yes	No	Yes	No	No
Pressure Devices	No	No	No	No	Yes	No	No
Antibiotics	No	No	Yes	No	Yes	Uncertain	Uncertain

Group + variance = study specified some measure of variance
Excluded: Wilson (background study)
Tung et al. (case report)
Goldin et al. (background study)
[a] There is possible confounding in patient age between the study groups. Patients who received sham therapy were statistically significantly older (73 years) than patients in the treatment group receiving
600 Hz therapy (59 years, p <.05).

5.3.2 Controlled Studies

[Page 116—add this after the last paragraph on the page]

In a recent single-blinded RCT, Baker et al.[27] treated 80 patients with spinal cord injuries who had surgical or decubitus ulcers. Twenty patients (with 67 lesions) received asymmetrical biphasic AC therapy, 21 (with 58 lesions) received symmetrical biphasic AC therapy, 20 (with 42 lesions) received minimal AC for 30-minute sessions three times daily for four weeks or until healing. A control group of 19 patients (with 25 lesions) received sham therapy for four weeks. The investigators reported healing in terms of an overall weekly mean healing rate (the percentage of lesion area healing divided by the total time for healing in days multiplied by 7 [days/week].) The weekly healing rates did not significantly differ between the groups (36% ±6% [SE] for the asymmetrical biphasic group, 30% ±5% for the symmetrical biphasic group, 23% ±5% for the minimal stimulation group, and 33% ±7% for the control group). The investigators performed multiple regression analyses of patient and ulcer characteristics (e.g., gender, age, ethnicity, onset of spinal cord injury, level of injury duration of ulcer, albumin concentration, hemoglobin level, standard ulcer treatment, ulcer location, initial ulcer area, and initial healing rate) and found that none of them affected healing. This study has many flaws. First, the investigators combined different types of lesions (i.e., decubitus and surgical ulcers). Second, because they did not specify the stage of the lesions, one cannot determine the severity of the ulcer (vascular compromise) and its effect on healing. Third, the study appears confounded by the presence of infection in some lesions. Fourth, the study appears confounded by the use of different topical/cleansing agents and dressings (e.g., sulfadiazine cream, occlusive dressing, wet-to-dry with saline solution dressing, dry dressing) within each group of patients and between the groups. The investigators themselves acknowledged that the lack of statistical differences in the mean healing rates among the four treatment groups “was probably due to the large variability in the data.” The flaws in this study probably confounded the outcomes.

5.4.2 Controlled Studies

[Page 119—add this after the last paragraph on the page]

In a recent double-blinded RCT, Kenkre et al.[28] treated 19 patients with venous leg ulcers. Five patients received PEE therapy at 600 Hz, five received PEE therapy at 800 Hz, and nine received sham therapy for 30-minute daily sessions (five times/week) for a minimum of 30 days. The trend for healing appeared better in the placebo group and 800 Hz treatment group than in the 600 Hz treatment group. The reduction in ulceration size statistically significantly decreased from a mean of 119 mg (weight of paper measuring the surface area of the lesion) to 78 mg at 50 days after initiation of therapy. The mean weights of paper decreased from 81 mg to 30 mg in the 800 Hz treatment group, but increased from 63 mg to 103 mg in the 600 Hz group. However, these results may be confounded because patients in the sham group were statistically significantly older (73 years) than those in the 600 Hz treatment group (59 years, $p < .05$).**

** Because these measurements were made in terms of the weight of the paper cutout representing lesion size and because we do not know the weight of the paper per mm^2, we cannot calculate the normalized healing rate (?). (See section 6.1.)

Table 5.3. Outcomes Reported by Investigators in Alternating Current and TENS Studies of Wound Healing

[Page 126—addition of Baker et al. 1996 study]

Study	Electrical Stimulation	Study Type	Number of Patients or Ulcers	% Patients Healed	Other Reported Outcomes
Baker et al.[29] (1996)	AC[a]	RCT	Decubitus + surgical ulcers: 20 asymmetric vs. 21 symmetric vs. 20 minimal stim vs. 19 sham	52% (asymmetric) 57% (symmetric) 43% (min stim) 24% (sham)[b]	Weekly healing rates: No statistically significant differences 36% ±6% (SE) for asymmetric biphasic AC 30% ±5% symmetric biphasic AC 23% ±5% minimal stimulation AC 33% ±7% sham (control)
Stefanovska et al. (1993)	AC	RCT	Decubitus ulcers: 82 AC vs. 18 LIDC vs. 50 control	Not available	Theta (?) values in %/day: ?(AC) = 5.43 ±4.4% (SD); ?(LIDC) = 3.11 ±3.83%; ?(control) = 2.21 ±3.27% Normalized healing rates for AC significantly greater than control; pulsed current significantly greater than control
Lundeberg et al. (1992)	(T)ENS	Double-blind RCT	Diabetic ulcers: 32 TENS vs. 32 sham	@ 12 weeks: 42% TENS vs. 15% sham	Percentage of ulcers healed at: 2 weeks—0% TENS, 4% sham 4 weeks—12% TENS, 7% sham 8 weeks—25% TENS, 11% sham 12 weeks—42% TENS, 15% sham
Karba et al. (1991)	AC	Case series	Lesions: 82 vascular, 14 decubitus, 17 posttraumatic	95% of all wounds healed (unspecified time)	Complete healing: Vascular lesions = 90.6% healed by 10 weeks, Decubitus lesions = 100% healed by 5.5 weeks Theta (?) values (per week): ?(vascular) = 0.47 ±0.09 (SE), ?(decubitus) = 0.83 ±0.33, ?(post-traumatic) = 1.02 ±0.26
Frantz (1990)	TENS	Case series (pilot study)	Decubitus ulcers: 4 TENS	25% healed @ 4 weeks	—
Kaada and Emru (1988)	TENS	Case series	Lepromatous lesions: 32 TENS	59% healed @ 12 weeks	Mean healing time = 5.2 weeks Mean healing index = 1.0 cm^3/week Mean healing index in tuberculoid type 3 times higher than lepromatous type

Table 5.3. Outcomes Reported by Investigators in Alternating Current and TENS Studies of Wound Healing (continued)

Study	Electrical Stimulation	Study Type	Number of Patients or Ulcers	% Patients Healed	Other Reported Outcomes
Alon et al. (1986) [Abstract]	TENS	Case series	Diabetic foot ulcers: 15 TENS	80% healed (mean 11.1 weeks)	No significant correlation between pre-existing duration of ulcers and healing time; no significant correlation between initial ulcer size and healing time
Barron et al. (1985)	TENS	Case series	Decubitus ulcers: 6 TENS	22.2% healed @ 3 weeks	Significant difference between means of initial lesion size and final reported sizes
Kaada (1983)	TENS	Case report	Mixed lesions/ulcerations: 10 TENS	70% healed @ 22 weeks	—
Westerhof and Bos (1983)	TENS	Case report	Neurotrophic facial ulcers: TENS	Healed @ 6 weeks	—

[a] Asymmetrical biphasic, symmetrical biphasic, minimal amplitude (4 mA) AC

[b] Percentage of lesions healed in an unspecified period of time

Excluded: Lundeberg et al. 1988: study of circulation in reconstructive skin flaps
Kjartansson and Lundeberg 1990: study of circulation in reconstructive skin flaps
Finsen et al. 1988: study of prevention of repeated lower extremity amputation

Table 5.4. Outcomes Reported by Investigators in Pulsed Electromagnetic Induction Studies of Wound Healing

[Page 128—Addition of Kenkre et al. 1996 study]

Study	Electrical Stimulation	Study Type	Number of Patients or Ulcers	% Patients Healed	Other Reported Outcomes
Kenkre et al.[30] (1996)	PEE	Double-blind RCT	Venous ulcers: 5 PEE (600 Hz) vs. 5 PEE (800 Hz) vs. 9 sham	(600 Hz) PEE: 20% @ 7.1 wks (800 Hz) PEE: 20% @ 7.1 wks Sham: 22% @ 7.1 wks	The mean size of ulcer was measured in the weight of the paper cutout that was traced over the ulcer @ 30 days after initial therapy: 600 Hz PEE worsened from 63 mg to 111 mg, 800 Hz PEE improved from 81 mg to 50 mg, sham improved from 119 mg to 93 mg; @ 50 days after initial therapy: 600 Hz PEE worsened from 63 mg to 103 mg, 800 Hz PEE improved from 81 mg to 30 mg, sham improved from 119 mg to 78 mg
Salzberg et al. (1995)	PEE	Double-blind RCT	Stage II decubitus ulcers: 10 PEE vs. 10 sham	PEE: 90% @ 3 wks; sham: 100% @ 11.9 wks	Median % patients healed at 1 wk significantly greater for PEE than sham; PEE healed in median of 13.0 days vs. 31.5 days for sham
			Stage III decubitus ulcers: 5 PEE vs. 5 sham	@ 12 weeks: 60% PEE; 0% sham	—
Tung et al. (1995)	PEE	Case report	Stage IV decubitus ulcers: 4 PEE	All healed	—
Stiller et al. (1992)	PEMF	Double-blind RCT	Venous ulcers: 18 PEMF vs. 13 sham	Not available	Significant difference in percentage of wound surface healed: PEMF lesions decreased mean of 47.1% vs. 48.7% increase in sham
Todd et al. (1991)	PEMF	Double-blind RCT	Venous ulcers: 10 PEMF vs. 9 sham	Not available	No significant difference in healing rates of groups; 22.0% reduction for PEMF, 9.1% reduction for control
Itoh et al. (1991)	PEE	Case series	Stage II decubitus ulcers: 9 PEE; Stage III decubitus ulcers: 13 PEE	Stage II: 100% @ 6 wks; Stage III: 100% @ 22 wks	—

Table 5.4. Outcomes Reported by Investigators in Pulsed Electromagnetic Induction Studies of Wound Healing (continued)

Study	Electrical Stimulation	Study Type	Number of Patients or Ulcers	% Patients Healed	Other Reported Outcomes
Ieran et al. (1990)	PEMF	Double-blind RCT	Venous ulcers: 18 PEMF vs. 19 sham	@ 90 days: 66.6% PEMF; 31.5% sham	Significantly more patients healed after 90 days with PEMF than sham; Significantly more patients healed 1 year posttherapy with PEMF (88.8%) than sham (42.1%); PEMF lesions healed in average of 71 days vs. 76 days for sham
Jeran* et al. (1987)	PEMF	Double-blind RCT	Venous ulcers: 11 PEMF vs. 11 sham	PEMF: 90.9% in mean of 71 days; sham: 45.5% in mean of 78 days	—

* Preliminary study of Ieran et al. 1990

Excluded: Goldin et al. 1981: study of effect on donor sites for medium-thickness split-skin grafting
Wilson 1972: study of soft-tissue (non-wound) healing

6.2.3 Meta-Analysis of Complete Wound Healing

[Page 147—paragraph under this heading should read . . .]

We used nine controlled studies obtained from our literature search in our meta-analysis of complete wound healing.*** These studies and relevant data are shown in **Table 6.8**. Details of this table are similar to those described for **Table 6.6**. Our strategy for the meta-analysis of complete healing was similar to that described for the normalized healing rate.

*** In this updated version, we identified two other RCTs (Baker et al. 1996 and Kenkre et al. 1996), bringing the total to 11. However, we did not perform another meta-analysis, which would have included these newly added RCTs, because the publication bias (section 6.2.4) indicated that it would not affect the outcome. According to the Rosenthal method, 31 to 67 studies with nonsignificant results would be needed to overturn the meta-analysis of complete wound healing; according to the Orwin method, 31 to 33 studies with nonsignificant results. Therefore, one additional RCT would not affect the meta-analysis.

Table 6.3. Normalized Healing Rates for Alternating Current and TENS Stimulation Studies of Wound Healing

[Page 158—addition of Baker et al. 1996 study]

Study	Stimulation	Study Type	Lesions	Treatment Group	Number Patients or Lesions	Initial Wound Size	Mean Normalized Healing Rate (?)	95% CI around Mean ?	Statistical Significance
Baker# et al.[31] (1996)	AC	Single-blind RCT	Mixed: Decubitus + Surgical	AC (asymmetric) AC (symmetric) AC (minimal) Sham (placebo)	20 21 20 19	6.6 cm^2 2.4 cm^2 8.5 cm^2 8.6 cm^2	— — — —	— — — —	— — — —
Stefanovska et al. (1993)	AC	RCT	Decubitus	AC DC Standard	82 18 50	12.0 cm^2 12.4 cm^2 16.6 cm^2	0.3801[c] 0.2177 0.1547	.3461 to .4141 .1545 to .2809 .1223 to .1871	Significant* NS*
Lundeberg et al. (1992)	TENS	Double-blind RCT	Diabetic	TENS Sham (placebo)	32 32	24.2 cm^2 22.0 cm^2	0.0846[b] 0.0473	.0640 to .1007 .0283 to .0663	NS
Karba et al. (1991)	AC	Case series	Decubitus	AC	14	1.03 cm^2	0.8300[c]	0.1862 to 1.4768	—
			Vascular	AC	32	1.77 cm^2	0.4700[a]	.2936 to .6464	—
Frantz (1990) [Pilot study]**	TENS	Case series	Decubitus	TENS	4	11.3 cm^2	0.1603[a]	-.4801 to +.8009	—
Kaada and Emru (1988)	TENS	Case series	Lepromatous	TENS	32	5.2 cm^3	0.8350[b] $?_{vol}$	0.6696 to 1.0003	—
Alon et al. (1986) [Abstract]	TENS	Case series	Diabetic	TENS	15	—	—	—	—
Barron et al. (1985)	TENS	Case series	Decubitus	TENS	6	5.09 cm^2	1.4827[a]	0.7468 to 2.2185	—

Case studies excluded

* Compared to standard therapy

** Insufficient data in preliminary RCT for analysis

\# Theta calculations not possible because investigators did not provide sufficient data for duration of healing process

[a] Theta calculations for study based on complete healing time (or single point)

[b] Theta calculations for study based on wound sizes at different time intervals

[c] Theta values specified by investigators

NS = nonsignificant;

— = not specified or not applicable

Table 6.4. Normalized Healing Rates for Pulsed Electromagnetic Induction Stimulation Studies of Wound Healing

[Page 159—addition of Kenkre et al. 1996 study]

Study	Stimulation	Study Type	Lesions	Treatment Group	Number Patients or Lesions	Initial Wound Size	Mean Normalized Healing Rate (?)	95% CI around Mean ?	Statistical Significance
Kenkre et al.[32] (1996)	PEE	Double-blind RCT	Venous	PEE (at 600 Hz) PEE (at 800 Hz) Sham (placebo)	5 5 9	63 mg# 81 mg# 119 mg#	— — —	— — —	—
Salzberg et al. (1995)	PEE	Double-blind RCT	Decubitus (stage II)	PEE Sham (placebo)	10 10	15 cm^2 (median) 33 cm^2 (median)	1.4740[a] 0.5209	1.3114 to 1.6370 0.1488 to 0.6740	Significant
			Decubitus (stage III)	PEE Sham (placebo)	5 5	— —	— —	— —	—
Stiller et al. (1992)	PEMF	Double-blind RCT	Venous	PEMF Sham (placebo)	18 13	7.25 cm^2 7.66 cm^2	+0.0824[a] -0.0754	.0596 to .0975 -.0984 to +.0082	Significant
Todd et al. (1991)	PEMF	Double-blind RCT	Venous	PEMF Sham (placebo)	10 9	83.5 cm^2 53.8 cm^2	0.4753[a] 0.0148	No variance measures specified	—
Itoh et al. (1991)	PEE	Case series	Decubitus (stage II)	PEE	9	5.56 cm^2	3.1002	1.7377 to 4.4627	—
			Decubitus (stage III)	PEE	13	8.78 cm^2	0.9614[a]	0.2683 to 1.6546	—
Ieran et al. (1990)	PEMF	Double-blind RCT	Venous	PEMF Sham (placebo)	18 19	— —	— —	— —	—
Jeran* et al.	PEMF	Double-blind RCT	Venous	PEMF Sham (placebo)	11 11	— —	— —	— —	—

Case studies excluded.

* Preliminary early study of Ieran et al. (1990)

These measurements are based on the weight of the paper cutout that traced the size of the lesion. Because we do not know the weight of the paper per cm^2, we cannot convert these values to cm^2 and thus cannot calculate the mean normalized healing rate.

[a] Theta calculations for study based on complete healing time (or single point)

— = not specified or not available

Table 6.5. Summary of Normalized Healing Rates in Controlled Trials of Electrical Stimulation for Chronic Wound Healing

[Page 160—addition of Baker et al. 1996 and Kenkre et al. 1996 studies]

Type of Lesion	Direct Current (DC)		Pulsed Current (PC)		Alternating Current (AC)/TENS		Pulsed Electromagnetic Induction (PEMI)	
	Study	? Significance	Study	? Significance	Study	? Significance	Study	? Significance
Venous Ulcers	Katelaris* (1987)	NS**	—	—	—	Significant	Kenkre[33] (1996) Stiller (1992) Todd (1991) Ieran (1990) Jeran (1987)	— Significant — — —
Decubitus Ulcers	Akers* (1984) Stefanovska (1993)	— NS	Wood (1993) Gentzkow (1991) Griffin (1991) Unger# (1991) Kloth (1988) Feedar# (1985)	Significant NS NS — Significant —	Stefanovska (1993)	—	Salzberg (1995)	Significant
Diabetic Ulcers	—	—	—	—	Lundeberg (1992)	No	—	—
Groups of Mixed Lesions or Unspecified Lesions	Carley (1985) Gault*** (1976) Wolcott*** (1969)	Significant — —	Gogia (1993) Feedar (1991)	— NS	Baker et al.[34] (1996)	—	—	—

* Nonrandomized comparative controlled study

** In one comparison, ? for LIDC + povidone <? for povidone alone

*** Randomized therapy ("embedded" RCT) on same patient

\# Abstract

NS = nonsignificant;

— = not specified or not available

9.2.1 Quality of Electrical Stimulation Studies

[Page 213—slight change to initial part of text in section 9.2.1]

We searched 17 databases and identified 43 studies of ES for the treatment of chronic wounds. They included:

- 6 studies using direct current stimulation (2 RCTs, 1 comparative, 2 case series [with embedded RCTs], and 1 case report);
- 14 studies using pulsed current stimulation (9 RCTs, 2 case series, and 3 case reports);
- 10 studies using AC or TENS stimulation (3 RCTs, 6 case series [1 with a very preliminary RCT], and 1 case report);
- 8 studies using pulsed electromagnetic induction devices (6 RCTs, 1 case series, and 1 case report); and
- 5 studies using implanted spinal cord stimulation (2 case series, 3 case reports) + 1 background article (on SCS for amputations).

These studies formed the basis of our qualitative and quantitative analyses.

Citations

For your convenience, each citation is provided in its entirety each time it is referenced in the text of the report.

1. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

2. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

3. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

4. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

5. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

6. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

7. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

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14. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

15. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

16. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

17. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

18. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

19. ECRI. Spinal cord stimulation for relief of neurological pain [technology assessment report]. Plymouth Meeting (PA): ECRI. Forthcoming.

20. ECRI. Spinal cord stimulation for cardio- and peripheral vascular pain [technology assessment report]. Plymouth Meeting (PA): ECRI. Forthcoming.

21. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

22. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

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24. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

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26. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

27. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

28. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

29. Baker LL, Rubayi S, Villar F, Demuth SK. Effect of electrical stimulation waveform on healing of ulcers in human beings with spinal cord injury. Wound Repair Regen 1996 Jan-Mar;4(1):21-8.

30. Kenkre JE, Hobbs FD, Carter YH, Holder RL, Holmes EP. A randomized controlled trial of electromagnetic therapy in the primary care management of venous leg ulceration. Fam Pract 1996 Jun;13(3):236-41.

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